

1090521

Section. 5 510(k) Summary

Company Name: Cardiovascular Systems, Inc.
651 Campus Drive
St. Paul, MN 55112

MAR 20 2009

Contact: David D. Brooke

Phone: (651) 259-2061

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Summary Date: February 25, 2009

Trade Name: 3X Solid Crown Diamondback 360°™ Orbital Atherectomy System

Common Name: Peripheral Atherectomy Device

Classification Name: Peripheral Atherectomy Catheter (21 CFR 870.4875; Product Code: MCW)

Predicate Device:

510(k) Number: K072748
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360°™ Orbital Atherectomy System

510(k) Number: K071350
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Diamondback 360°™ Orbital Atherectomy System

510(k) Number: K081944
Manufacture: Cardiovascular Systems, Inc.
Trade Name: Sidewinder Diamondback 360°™ Orbital Atherectomy System

5.1 Description of Device

The Diamondback 360°™ Orbital Atherectomy System (OAS) with 3X Solid Crown is intended for use in the treatment of peripheral arteries and A-V graft (shunt) stenosis.

OAS provides a method of removing stenotic material from peripheral arteries and A-V grafts. OAS applies a diamond coated, eccentrically rotating sanding surface to ablate

stenotic material. The resulting particles of removed stenotic material are very small and can be absorbed by the body.

The Diamondback 360° Orbital Atherectomy System consists of the following three significant components:

- 1) Orbital atherectomy device
- 2) Orbital atherectomy controller, and
- 3) Atherectomy guidewire.

This 510(k) is for the same device with modifications to the crown ,shaft and guidewire for improved sanding efficiency.

5.2 Intended Use

The 3X Solid Crown Diamondback 360°™ Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

5.3 Technology

The 3X Solid Crown Diamondback 360°™ Orbital Atherectomy System provides a method of removing occlusive atherosclerotic or stenotic material. The OAS applies a diamond coated, eccentrically rotating sanding surface to ablate stenotic tissue. The resulting particles of removed stenotic tissue are very small and can be absorbed by the body. This same technology was cleared to market for use in peripheral arteries in 510(k) K071350, A-V grafts per K071427, Solid Crown per K072748, and Solid Crown with Sidewinder Shaft per K081944.

5.4 Conclusions

The 3X Solid Crown Diamondback 360°™ Orbital Atherectomy System is substantially equivalent to the predicate devices. Laboratory and animal tests were performed to support the safety profile of the modification to the Diamondback 360°™ Orbital Atherectomy System. No new questions of safety or effectiveness were raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cardiovascular Systems, Inc.
c/o Mr. David Brooke
Senior Regulatory Manager
651 Campus Drive
St. Paul, MN 55112

MAR 20 2009

Re: K090521
3X Solid Crown Diamondback 360° Orbital Atherectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: February 25, 2009
Received: February 26, 2009

Dear Mr. Brooke:

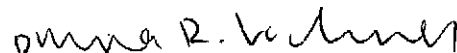
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section. 4 Indications For Use Statement

510(k) Number: K090521

Device Name: 3X Solid Crown Diamondback 360° Orbital Atherectomy System

Indications for Use:

The Diamondback 360°™ Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The OAS is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Volkmann
Special Agent in Charge
Division of Cardiovascular Devices

510(k) Number K090521